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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,981	06/24/2003	John D. Roback	050508-1031	2039

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

28

Office Action Summary	Application No.	Applicant(s)	
	10/602,981	ROBACK ET AL	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,10-13,15-33 and 35-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,10-13,15-33 and 35-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on April 18, 2005. Claims 1-8, 10-13, 15-33 and 35-46 are pending.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the washer (140) as described in the specification. In the specification, Applicants describe the washer in terms of its size, shape and function (specification page 10). However, in the drawings it appears that the reference character (140), which is described as the washer, points to the filter vessel system and not to a structural element having the size and shape to allow reagents to be washed from the filter vessel. Clarification is requested.

In response to the previous Office Action, Applicants stated that a corrected drawing sheet was attached. The Examiner did not find a corrected drawing sheet with the papers submitted on April 18, 2005. Applicants are requested to resend the corrected drawing sheet.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 6, 7, 13, 15-16, 18-22, 39-45 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,692,702 to Burshteyn et al.

Burshteyn et al teach an apparatus for biological sample preparation and analysis, specifically blood cell analysis. The apparatus of Burshteyn et al comprises sample filter vessel (24). The filter vessel comprises a microporous hollow fiber membrane having a plurality of pores. The porous filter allows the vessel to have an irregular bottom. The porous membrane may be a nylon membrane, having a pore size of 0.1-5 microns, as recited in claims 6 and 7 (col. 7, lines 43-59). At col. 15, lines 55-59, Burshteyn et al teach that a vacuum forces causes components of the blood to pass through the filter while retaining cells of interest, as recited in claim 16. A fluorescently-labeled antibody (reagent) is added to the blood sample to form a test mixtures, as recited in claims 15 and 19-22. The test mixture is analyzed with a flow cytometer to quantitatively measure the amount of antigen-specific antibody associated with each cell in the test sample as recited in claims 9, 13, 14 (col. 16, lines 44-52).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 8, 10-12, 15, 17-31, 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al in view of US patent 5,308,990 to Takahashi et al.

Yaremko et al disclose an automated blood analysis system. The system comprises a microcolumn (122), incubator (200), centrifuge (500), pipette assembly (400), washer (406, 410) and imaging system (606), as recited in claims 1-5. The incubator holds containers/receptacles while reagents and fluids are being dispensed into the containers and incubates the containers, (col. 5, lines 39-42). The containers/receptacles are microcolumns having a filter through which the assay sample travels. The filters provide an irregular "bottom" for the vessel, as recited in claim 1. The centrifuge rotates the containers within it (containing the assay sample) to push the cellular material in the sample through the filter material and thus separate the sample, as recited in claims 3, 8, 11 and 12 (col. 13, line 61 – col. 15, line 3). At col. 14, line 61 to col. 15, line 3, the reference discloses centrifuging at a lower speed to push the cells toward the filter and to increase cell to cell contact to achieve maximum reactivity, as recited in claims 24-26, 35, 36 and 38. The imaging system comprises a camera (644) for capturing an image of the analysis of the sample, as recited in claim 4 (col. 15, line 48 – col. 16, line

21). The pipette assembly comprises a pipette (402) and a robot arm (404), as recited in claim 5 (col. 13, lines 1-12). Yaremko et al disclose that the system is used for analyzing blood samples and for identifying antibodies and antigens as recited in claim 10.

With respect to the method of claims 23, 28 and 29, Yaremko et al disclose providing a filter vessel; adding a blood sample and reagent to the vessel, centrifuging the vessel and analyzing the centrifuged components. With respect to claim 31, Yaremko et al disclose that the filter in the microcolumn may be a porous gel material (col. 6, lines 21-32).

Yaremko et al differ from the instant invention in that the reference fails to teach a flow cytometer as the image acquisition system.

Takahashi et al teach that flow cytometers can be used in immunological measurement methods to determine antigen-antibody reactions and agglutination from the antigen-antibody reactions (col. 1, lines 37-53). It would have been obvious to one of ordinary skill in the art to substitute the camera system of Yaremko et al for a flow cytometer to provide a means to determine antigen-antibody interactions and agglutination in immunological assays.

5. Claim 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yaremko et al and Takahashi et al and further in view of US Patent 6,008,040 to Datar.

The disclosures of Yaremko et al and Takahashi et al are described above.

Neither Yaremko et al nor Takahashi et al teach the particular filter materials recited in claims 32-33.

Datar teaches efficient separation of cells, cellular materials and proteins.

Specifically, Datar teaches separation devices such as bead columns. Further, Datar teaches that cellulose acetate beads, polyesters, and nylons are suitable for use in separation columns due to their specific chemistries on their contacting surfaces (col. 4, lines 24-41). It would have been obvious to one of ordinary skill in the art to use filter materials, such as cellulose acetates, polyesters, and nylons as the filter material in the microcolumn of Yaremko et al. These materials are known to be suitable in the separation of cellular material. The ordinarily-skilled artisan would have expected that these filter materials would perform sufficiently in separating blood cells.

Terminal Disclaimer

6. The terminal disclaimer filed on March 24, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on US application 09/773,826 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

7. Applicant's arguments filed on April 18, 2005 have been fully considered but they are not persuasive.

With respect to the anticipation rejection over Burshteyn et al, Applicants argue that the filing date of Burshteyn et al (July 7, 2000) is after the effective filing date of the instant application, since the instant application claims priority to provisional application 60/179,248 filed on January 31, 2000. The Examiner notes that the instant application is a continuation-in-part of the provisional application (60/179,248). The Examiner checked the provisional application and did not find support for many of the current claim limitations. Specifically, there is no support for a filter material chosen from polypropylene, cellulose nitrate, nylon, polyvinylidene fluoride or HPVM membrane. Further, there is no support in the provisional application for a flow cytometer image acquisition system. Applicants stated that support for the claims could be found at pages 3-5 and 10-11 of the provisional application. However, after reviewing the entire provisional application (note there are no page numbers in the provisional application), the Examiner found no such support. Thus, since the claims are not supported by the provisional application, the effective filing date is the actual filing date of the instant application – June 24, 2003. The Burshteyn et al reference has a

filing date before that of the instant application and may therefore be used as prior art against applicants' claims.

With respect to the Yaremko et al reference, the anticipation rejection has been withdrawn in view of Applicants' amendments to recite the particular filter material being used and that the image acquisition system is a flow cytometer. With respect to the particular filter materials, Applicants argue that the filter materials of Datar are used for their separation characteristics, while the filters materials of the instant application are used to even spreading. In response, the Examiner notes that MPEP 2144 states that rationale different from applicant's is permissible. Specifically, the manual states, "It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by Applicant". Thus, the fact that Datar uses the filter materials for a reason different than Applicants is immaterial. Datar teaches that the materials are good for separation columns due to their specific chemistries on contacting surfaces. Thus providing adequate motivation for one of ordinary skill in the art to use them in Yaremko et al.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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